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Safety and effectiveness of bilateral continuous sciatic nerve block for bilateral orthopaedic foot surgery: A cohort study

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Abstract: **BACKGROUND:** Severe postoperative pain is a major problem after unilateral and bilateral foot surgery. Continuous regional anaesthesia is often used for unilateral surgery. However, for bilateral surgery, the incidence of complications of continuous bilateral compared with unilateral regional anaesthesia is unknown. **OBJECTIVES:** To assess the incidence of catheter-related complications of bilateral compared with unilateral continuous regional anaesthesia. **DESIGN:** A prospective observational study. **SETTING:** Bellinzona Regional Hospital, a tertiary teaching hospital. **PATIENTS:** Patients ($n = 130$) scheduled for elective bilateral or unilateral hallux valgus repair treated with continuous popliteal sciatic nerve block using a continuous infusion of ropivacaine 0.15% at 5 ml h for each popliteal catheter by elastomeric pumps. **INTERVENTIONS:** The incidence of catheter-related complications, effectiveness, pain levels at rest and with motion, patient satisfaction for the first three postoperative days and the incidence of ambulatory visits or readmissions after discharge were measured. A follow-up for neurological or other complications related to regional anaesthesia was performed 6 to 8 weeks after surgery. **MAIN OUTCOME MEASURE:** The incidence of catheter-related complications comparing bilateral with unilateral continuous sciatic popliteal nerve block. **RESULTS:** There were no differences in the incidence of catheter-related complications between the groups. Pain scores at rest and with motion were comparable between the groups. All patients were fit for discharge home 3 days after surgery. Patient satisfaction was similar between the groups. There were no unplanned ambulatory visits or readmissions due to complications in either group. No complications related to regional anaesthesia were reported during the follow-up. **CONCLUSION:** The complication rate, effectiveness and patient satisfaction of bilateral continuous popliteal sciatic nerve block was comparable with unilateral continuous sciatic popliteal nerve block. The follow-up showed that bilateral continuous sciatic popliteal nerve block does not increase the complication rate. However, an outpatient-based study should confirm these data prior to introduction in the ambulatory setting.

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ORIGINAL ARTICLE

Safety and effectiveness of bilateral continuous sciatic nerve block for bilateral orthopaedic foot surgery

A cohort study

Andrea Saporito, Gianfranco J. Petri, Evelina Sturini, Alain Borgeat and José A. Aguirre

BACKGROUND Severe postoperative pain is a major problem after unilateral and bilateral foot surgery. Continuous regional anaesthesia is often used for unilateral surgery. However, for bilateral surgery, the incidence of complications of continuous bilateral compared with unilateral regional anaesthesia is unknown.

OBJECTIVES To assess the incidence of catheter-related complications of bilateral compared with unilateral continuous regional anaesthesia.

DESIGN A prospective observational study.

SETTING Bellinzona Regional Hospital, a tertiary teaching hospital.

PATIENTS Patients ($n = 130$) scheduled for elective bilateral or unilateral hallux valgus repair treated with continuous popliteal sciatic nerve block using a continuous infusion of ropivacaine 0.15% at 5 ml h^{-1} for each popliteal catheter by elastomeric pumps.

INTERVENTIONS The incidence of catheter-related complications, effectiveness, pain levels at rest and with motion, patient satisfaction for the first three postoperative days and the incidence of ambulatory visits or readmissions after discharge were measured. A follow-up for neurological

or other complications related to regional anaesthesia was performed 6 to 8 weeks after surgery.

MAIN OUTCOME MEASURE The incidence of catheter-related complications comparing bilateral with unilateral continuous sciatic popliteal nerve block.

RESULTS There were no differences in the incidence of catheter-related complications between the groups. Pain scores at rest and with motion were comparable between the groups. All patients were fit for discharge home 3 days after surgery. Patient satisfaction was similar between the groups. There were no unplanned ambulatory visits or readmissions due to complications in either group. No complications related to regional anaesthesia were reported during the follow-up.

CONCLUSION The complication rate, effectiveness and patient satisfaction of bilateral continuous popliteal sciatic nerve block was comparable with unilateral continuous sciatic popliteal nerve block. The follow-up showed that bilateral continuous sciatic popliteal nerve block does not increase the complication rate. However, an outpatient-based study should confirm these data prior to introduction in the ambulatory setting.

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Introduction

Single-shot and continuous perineural blocks have gained increasing popularity as either an adjunct or the main technique for perioperative pain control in foot and ankle surgery. These techniques have been shown to facilitate earlier hospital discharge by reducing postoperative nausea and pain. Foot surgery is an important field of orthopaedic surgery and single-injection popliteal

sciatic nerve block provides analgesia for up to 24 h with the need for oral opioids for pain control thereafter. The use of a sciatic perineural catheter at the popliteal level extends opioid-free analgesia for up to 48 h and facilitates early discharge after foot surgery.^{1,2} This ambulant management has been shown to reduce hospital stay and total hospital costs without

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compromising patient outcomes or increasing morbidity, not only for foot surgery but also for major joint surgery.^{3,4}

Bilateral foot surgery is often performed under general or spinal anaesthesia followed by systemic analgesia.⁵ Bilateral peripheral blocks are used rarely, probably because of the long-lasting block of both extremities and the increased amount of local anaesthetic needed for a bilateral block.^{6,7}

To date, no study has examined this issue in the setting of bilateral continuous popliteal sciatic nerve block for anaesthesia and postsurgical analgesia in foot surgery. The aim of the present study was to assess whether bilateral continuous popliteal sciatic nerve block for foot surgery leads to more complications than a unilateral approach in an inpatient setting. The primary endpoint of the study was the incidence of catheter-related complications (catheter failure due to pump malfunction or catheter obstruction, inadequacy of analgesia due to catheter misplacement or displacement, persistent motor block, insertion point inflammation or infection and stumbling or falling)^{8–10} comparing bilateral with unilateral continuous sciatic popliteal nerve block. The secondary endpoints were anaesthetic block success rate, pain at rest and with motion, incidence of procedural complications (acute systemic toxicity), patient satisfaction, the incidence of ambulatory visits or readmissions after discharge and the incidence of neurological complications or complications related to regional anaesthesia in a follow-up 6 to 8 weeks after surgery.

Materials and methods

After ethical committee approval (Ethical Committee No. CE 2607) by the Comitato Etico Cantonale, Bellinzona, Canton Ticino, Switzerland and written informed consent, patients of either sex with American Society of Anesthesiologists' (ASA) physical status 1 to 3 scheduled for elective bilateral and unilateral hallux valgus repair (Chevron and Akin techniques) were included prospectively in this cohort study. Patients were allocated according to diagnosis to a unilateral continuous popliteal sciatic nerve block group (ucPNB group, $n=65$) or a bilateral continuous popliteal sciatic nerve block group (bcPNB group, $n=65$). In accordance with the ethical committee and the surgical department, an inpatient protocol of 3 days, instead of the usual 2 days, was introduced to assess all possible complications of unilateral and bilateral continuous sciatic nerve block.

Exclusion criteria were known allergy to drugs used in the study, coagulopathy, known neuropathy, pregnancy, chronic pain, drug or alcohol abuse, psychiatric disease or mental retardation affecting compliance, evidence of ongoing sepsis or local skin or subcutaneous tissue infections at the popliteal fossa.

Standard monitoring was applied, and light sedation was provided using fentanyl $1\text{ }\mu\text{g kg}^{-1}$ and midazolam 1 to 2 mg intravenously, preserving responsiveness to verbal cues. In a lateral recumbent position, with the upper limb slightly flexed at both the hip and knee, skin disinfection was performed with a two-layer application of an alcoholic povidone-iodine solution (Betaseptic; Mundipharma, Basel, Switzerland) and sterile drapes were applied. After a first sterile diagnostic ultrasound scan (MyLab Five, Esaote, Italy) with a linear array transducer (5 to 13 MHz) in order to identify in a short axis view the exact point of the sciatic nerve division into the peroneal and tibial nerves, a 5-cm nerve block needle (Contiplex D, BBraun, Melsungen, Germany) was inserted under dynamic ultrasound visualisation and guided with an in-plane technique towards the sciatic nerve. A first anaesthetic bolus of 1.5% mepivacaine 20 ml was administered (Mepivacaine, Sintetica, Switzerland) approximately 1 cm proximal to the division point and its spread observed in real time to document distribution around the nerve. A perineural catheter (Contiplex set, BBraun, Melsungen, Germany) was inserted 4 cm beyond the tip of the needle and placed under the nerve with real-time observation of the catheter tip. The perineural catheter was subsequently connected to a filter (Perifix, BBraun, Melsungen, Germany) and then tested for negative aspiration and flow obstructions. Finally, the catheter was draped to the skin with a transparent dressing (Tegaderm; 3M, St. Paul, NM, USA). In the bilateral hallux valgus repair group, the identical procedure was repeated on the contralateral side.

Block success for the popliteal block was evaluated as described elsewhere.¹¹ Surgery was performed with no further sedation and ketorolac 30 mg was administered intravenously at the end of the procedure.

Patients were discharged to the ward if considered fit to bypass the postanesthesia care unit (PACU) if the modified Aldrete scale was at least 8, if pain was under control according to the numerical rating scale (NRS) less than 3 (0, no pain; 10, worst imaginable pain) and if postoperative nausea and vomiting (PONV) was absent.¹² Quality of analgesia was assessed hourly during the first 3 h, and thereafter daily, at rest and with motion (a 10-m walk distance with a weight-bearing capacity of half the patient's body weight).

Postoperative systemic analgesia consisted of oral diclofenac 50 mg twice daily and oral paracetamol 1 g every 6 h for the first three postoperative days. Additional oral oxycodone (Oxynorm, Mundipharma, Dublin, Ireland) 5 to 10 mg was administered if the NRS was at least 3 despite continuous regional analgesia.

In both groups, continuous regional analgesia was provided using a standard protocol consisting of a fixed-rate continuous infusion of ropivacaine 0.15% (Naropine; Astra Zeneca, Wilmington, DE, USA) at a rate of

5 ml h⁻¹ for each popliteal catheter, delivered by disposable elastomeric pumps (Easypump, BBraun, Melsungen, Germany) with a total capacity of 400 ml (80 h of local anaesthetic delivery). Infusions were started in all cases immediately after the end of surgery and before discharge to the ward.

Catheter-related complications, treatment efficacy, side effects or incidental problems with perineural catheters were documented if they occurred and were regularly checked through a standardised questionnaire every 24 h in both groups. This questionnaire was delivered each day to both groups by a study nurse and included pain assessment using NRS at rest and while walking; Bromage scale to assess the level of motor block; the presence of PONV; a specific inquiry about possible accidental stumbles or falls; signs of inflammation or infection; and the possibility of any other side effects or complications.

An anonymous satisfaction questionnaire was also given to all patients, addressing specific perceived aspects of the continuous regional analgesia protocol (effectiveness, appropriateness, safety, global management and assistance). The possible answers to each question were excellent, good, acceptable or insufficient.

Patients were discharged home on the third postoperative day after successful removal of the catheter, if there were no signs of inflammation or infection and if the NRS was less than 3 once the anaesthetic block had worn off. All patients were monitored by our study nurse during the first postoperative week for unscheduled ambulatory visits or readmissions. A clinical follow-up took place during the first postsurgical visit after 6 to 8 weeks, focusing on neurological complications and complications related to regional anaesthesia.

Statistics

In our experience with ucPNB for foot surgery and a previous pilot study (unpublished results), the incidence of ucPNB-related complications (catheter failure due to pump malfunction or catheter obstruction, inadequacy of analgesia due to catheter misplacement or displacement, persistent motor block, insertion point inflammation or infection, and stumbling or falling) in our department was 8.5%. From our experience with bilateral popliteal catheters and the good results with standard protocols for patient education to use these catheters and with follow-up at home,⁶ we hypothesised that the incidence of complications after bilateral foot surgery treated with bcPNB would be similar to ucPNB. The power analysis calculated a sample size of 40 patients per group to reject the null hypothesis with an α risk of 0.05 and a power of 0.8. To increase the power of our results and to compensate for possible drop-outs, we included 65 patients per group.

The unpaired *t*-test was used for parametric data, and the Mann–Whitney *U*-test was applied to nonparametric data. The Kolmogorov–Smirnov test was used to assess

normal distribution of data. A *P* value less than 0.05 was considered statistically significant. Results are given as mean \pm standard deviation (SD) for normally distributed variables or median and interquartile range (IQR) for nonnormally distributed variables. Statistical analysis was performed using SPSS version 17 (IBM, New York, USA) and Numbers '09 2.1 version (Apple Inc., Cupertino, CA, USA).

Results

A total of 130 patients were recruited between January and December 2012 and treated with an equal distribution of 65 cases per group. The two groups did not differ in their characteristics (Table 1). The mean duration of the surgical procedure was 37 \pm 12 min in the ucPNB group and 65 \pm 16 min in the bcPNB group (*P* < 0.001). No patient was lost at the follow-up and none had to be excluded from the study.

There was no difference in the incidence of catheter-related complications between the two groups. In the bcPNB group, postoperative continuous infusions had to be temporarily stopped for 1 h in two patients due to a persistent motor block of the ankle, compared with none in the ucPNB group (3.1 versus 0%, *P* = 0.149). In three patients in the bcPNB group and two patients in the ucPNB group, the catheter was accidentally dislodged on the third postoperative day (4.6 versus 3.1%, *P* = 0.656). No catheter insertion point inflammation or infection was observed, and no accidental stumbling or falling occurred during hospitalisation.

All blocks were successful after the first bolus. None of the patients required additional intraoperative analgesia or sedation. No procedural complications, allergic reactions to local anaesthetics or clinical signs of local anaesthetic systemic toxicity occurred.

Median (IQR) NRS at the end of surgery was similar between the groups [ucPNB group 2 (1.5); bcPNB group 0 (0); *P* = 0.540] and all patients matched criteria for PACU bypass and were discharged directly to the orthopaedic ward.

The efficacy of postoperative analgesia was similar in the two groups. There were no significant differences in pain level, either at rest or with motion, during the first 3 postoperative hours and during daily assessment. The need for and total dose of rescue opioids during the whole

Table 1 Patient characteristics

	bcPNB	ucPNB	<i>P</i>
Number	65	65	1.000
Sex (F:M)	59:6	58:7	0.731
Age (years)	49.6 \pm 15.8	51.5 \pm 13.8	0.480
ASA	2 (1)	2 (1)	1.000

Data are numbers, mean \pm SD or median (IQR). ASA, American Society of Anesthesiologists' Physical Status classification; bcPNB, bilateral continuous sciatic popliteal nerve block; ucPNB, unilateral continuous sciatic popliteal nerve block.

perineural infusion period of 80 h was similar between the groups (ucPNB group oxycodone cumulative dose 45 mg versus bcPNB 55 mg; $P=0.772$). There were no significant differences in the duration of motor block between the groups: ucPNB group Bromage score 1 (free movement of the ankle) 3.5 ± 0.28 h after the initial bolus versus 3.4 ± 0.32 in the bcPNB group ($P=0.855$). All patients were successfully mobilised on the first postoperative day, still having a Bromage score of 1, and were allowed to walk around accompanied, fully weight-bearing and with flat orthopaedic shoes. Due to an inconsistent slight reduction of sensation in the plantar region, the study protocol required crutches for safety reasons (Table 2).

Excluding the five cases of accidental catheter dislodgement early on the third postoperative day, continuous regional analgesia lasted in all patients for 80 h, with subsequent successful catheter removal and no need for additional analgesia (NRS ≤ 3 during the first 6 h after removal in all patients). In both groups, the inconsistent slight reduction of sensation in the plantar region disappeared within 1 h of removal of the catheter. The sterile dressing was not changed or modified by the nurses during hospitalisation.

All patients were successfully discharged home after catheter removal and there were no unscheduled ambulatory visits or readmissions in the first week after surgery. In the follow-up, no neurological complications or complications related to regional anaesthesia were reported.

Satisfaction rate was high and similar in both groups: median 3 (excellent) (IQR 1) in both groups.

Discussion

To our knowledge, this is the first study investigating the catheter-related complication rate and the effectiveness of analgesia of bilateral continuous popliteal sciatic nerve block for hallux valgus repair compared with unilateral popliteal sciatic nerve block.

In a survey of anaesthesiologists, there was a reluctance to send patients home with long-acting peripheral nerve

blockade of the lower limb, but not the upper limb.¹³ The foot drop after sciatic nerve block was not the concern of most surgeons because a splint or cast is often used. However, sending the patient home with a sensory deficit in the foot was an issue for most of the doctors. Therefore, we performed this study in an inpatient setting for 3 days to assess continuous block-related problems in a protected environment. In this setting, we found that bcPNB was equally well tolerated and effective in treating postoperative pain after bilateral hallux valgus repair compared with ucPNB for unilateral procedures. The assumed 8.5% catheter-related complications might seem high but is in accordance with the many studies describing technical difficulties.^{8,9} Ilfeld *et al.*¹⁰ reported 30% of patients necessitating unscheduled phone calls after discharge due to clinical and technical problems. These authors also reported inadvertent catheter dislodgement in two of their 30 patients.

A comparison between continuous sciatic nerve block and single-shot nerve block with additional systemic analgesia for foot surgery has been analysed previously in different settings,^{2,10,14} with positive results in the continuous nerve block groups in respect of pain relief, reduced analgesic consumption, increased patient satisfaction and no increase in complication rates. In a prospective, randomised, double-blind, placebo-controlled trial of continuous infusion of bupivacaine for 72 h after major ankle and hindfoot surgery in 54 patients, Elliot *et al.*¹⁵ found lower pain scores and reduced analgesic consumption. However, they observed a low average pain score in both groups and challenged the additional extra time and costs involved in using an additional catheter. The differences in the pain scores compared with similar studies^{2,10,14} are explained by the use of strong oral analgesics including opioids, which were not declared in the study by Elliot *et al.*¹⁵ In addition, pain scores were assessed only at rest and by the patients themselves three times daily for 72 h.

In a recent review of neurological complications following peripheral nerve blocks, Brull *et al.*¹⁶ reported that the incidence of neuropathy following all types of peripheral nerve blockade was less than 3%, including one recorded permanent neurological injury. The reported incidences of neurological complications in studies specifically involving the sciatic nerve are very low, with no recorded permanent injury.^{10,17} Gartke *et al.*¹⁸ found a prevalence of 41% at 2 weeks, decreasing to 24% at 34 weeks in a prospective cohort study of 147 patients receiving a continuous popliteal block for foot and ankle surgery. However, this study has many drawbacks, such as the use of epinephrine added to the initial 40-ml ropivacaine 0.5% bolus, the varying technique for block performance without details about the correct use of ultrasound or nerve stimulation, and the

Table 2 Postoperative analgesia

	bcPNB	ucPNB	P
NRS day 1 rest	0 (2)	2 (1.5)	0.683
NRS day 1 walk	3 (2)	3 (1.5)	0.755
Rescue opioids day 1	12.3%	7.7%	0.381
NRS day 2 rest	0 (2)	2 (2)	0.721
NRS day 2 walk	3 (2)	3 (2)	1.000
Rescue opioids day 2	3.1%	4.6%	0.656
NRS day 3 rest	0 (0)	2 (2)	0.105
NRS day 3 walk	3 (1.5)	3 (1.5)	1.000
Rescue opioids day 3	3.1%	4.6%	0.656

Data are median (IQR) or percentage of patients. bcPNB, bilateral continuous sciatic popliteal nerve block; NRS, numerical rating scale; ucPNB, unilateral continuous sciatic popliteal nerve block.

lack of preoperative testing to exclude preexisting neurological diseases.

The use of bilateral single-shot ankle blocks or blocks after general anaesthesia even for outpatients after bilateral hallux valgus surgery has also been described.¹⁹ According to our experience, there is a high level of unscheduled visits or readmissions due to pain on the first two postoperative days. This is in accordance with current literature describing unplanned hospital admission rates of 4 to 13% even after single-shot regional anaesthesia.²⁰ These results indicate a need for more sophisticated analgesia methods in the ambulatory setting to maintain its financial advantage.

Current literature describes only single-shot bilateral sciatic nerve blocks despite the advantages of continuous regional anaesthesia over a single bolus.⁵ Ilfeld *et al.*¹⁰ found that continuous perineural block for 3 days after foot surgery was superior to single-shot sciatic popliteal nerve block regarding pain, opioid use and related side effects, with improvements in sleep quality and patient satisfaction. In a subsequent study, the authors demonstrated that additional patient-controlled bolus doses were associated with decreased local anaesthetic consumption and longer lasting analgesia.¹⁷

Several potential inherent risks have been described using continuous lower extremity blocks, such as falling and pressure ulcers due to numb extremities.^{6,21} We used a continuous infusion of ropivacaine at a low concentration (0.15%) to avoid possible muscle weakness and showed good postoperative pain control in both groups at low flow rates, leading to a well tolerated total dose of local anaesthetic for bilateral procedures. This strategy led to two cases of persistent motor block of the ankle in the bcPNB group, with minimal, inconsistent sensory reduction. However, according to the results of Ilfeld *et al.*,²² the relationship between concentration and flow rate has to be established for bilateral popliteal sciatic nerve block. In fact, the risks related to the use of continuous nerve block of the lower extremity remain underestimated.²³ In clinical trials on healthy volunteers, nerve blocks have been shown to impair proprioception, with joint stiffness possibly being responsible for falls.^{24,25}

Our results showed no difference in systemic complications or in complications due to persistent motor block between the groups.⁶ The ropivacaine doses of 7.5 mg h⁻¹ for unilateral and 15 mg h⁻¹ for bilateral continuous popliteal sciatic nerve block were well below the maximum recommended ropivacaine dose of 37.5 mg h⁻¹ in our country and below the dose used in previous studies analysing the plasma concentration of free ropivacaine after regional anaesthesia.^{26,27} Borghi *et al.*^{28,29} described the use of continuous ropivacaine 0.5% through a sciatic catheter for phantom limb pain treatment

without any report of systemic toxicity. In addition, the use of bilateral nerve blocks has been reported as a well tolerated technique for major joints in hospitalised³⁰ and ambulant patients.³¹

Limitations of the study

Due to logistical difficulties of double-blinding and randomisation, this study had to be performed as a prospective cohort study because of ethical requirements to avoid an unnecessary second operation for bilateral hallux valgus. The study was designed in an inpatient setting to assess the potential problems of an ambulatory setting in a controlled and protected environment. However, the nurses did not assist the patients in daily activities (mobilisation, taking care of elastomeric pumps and dressings and so on) to avoid bias, but a formal investigation in an outpatient setting is required to assess possible additional complications at home. Despite the fact that the number of patients was increased to improve the power, the results of the secondary endpoints must be interpreted with caution. Moreover, these results compare only two continuous regional anaesthesia regimens. A large number of inpatient and outpatient procedures are performed with single-shot regional anaesthesia using long-lasting local anaesthetics with or without additives. A comparison of single-shot and continuous regional anaesthesia for bilateral foot surgery needs to be performed to clarify whether a continuous regimen offers additional advantages. The measurement of free ropivacaine plasma concentrations was not undertaken because the total dose given was far below toxic range in studies using much higher doses.

In summary, this study showed that bilateral continuous sciatic popliteal nerve block was well tolerated and efficient in managing acute postoperative pain after bilateral foot surgery without increasing the risks described for a unilateral approach. However, further studies will be welcome to confirm these results in the ambulatory setting before this technique becomes a clinical practice in selected patients. Due to financial restrictions in healthcare, unilateral and bilateral hallux valgus surgery and other painful foot surgery will be performed routinely as daycase procedures. Therefore, standard education protocols^{6,32} for outpatient continuous regional anaesthesia with follow-up telephone contact by a pain nurse will be introduced to offer good pain therapy at home and avoid catheter-associated problems.

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